CLINICAL RESEARCH STUDIES

From the Society for Vascular Surgery

Endovascular repair compared with surveillance for patients with small abdominal aortic aneurysms

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Background: **Although repair of large abdominal aortic aneurysms (AAAs) is well accepted, randomized clinical trials have failed to demonstrate benefit for early surgical repair of small aneurysms compared with surveillance. Endovascular repair has been shown to be safer than open surgical repair in patients with large aneurysms, prompting a randomized trial of early endovascular repair vs surveillance in patients with small aneurysms.**
Methods: **We randomly assigned 728 patients (13.3% women; mean age, 71 ± 8 years) with 4 to 5 cm AAAs to early endovascular repair (366 patients) or ultrasound surveillance (362 patients). Rupture or aneurysm-related death and overall mortality in the two groups were compared during a mean follow-up of 20 ± 12 months.**
Results: **Among patients randomized to treatment, 89% underwent aneurysm repair. Among patients randomized to surveillance, 31% underwent aneurysm repair during the course of the study. After a mean follow-up of 20 ± 12 months (range, 0-41 months), 15 deaths had occurred in each group (4.1%). The unadjusted hazard ratio (95% confidence interval) for mortality after early endovascular repair was 1.01 (0.49-2.07, *P* = .98). Aneurysm rupture or aneurysm-related death occurred in two patients in each group (0.6%). The unadjusted hazard ratio was 0.99 (0.14-7.06, *P* = .99) for early endovascular repair.**
Conclusions: **Early treatment with endovascular repair and rigorous surveillance with selective aneurysm treatment as indicated both appear to be safe alternatives for patients with small AAAs, protecting the patient from rupture or aneurysm-related death for at least 3 years. (J Vasc Surg 2010;51:1081-7.)**

Aortic aneurysm repair is performed to prevent rupture, an event strongly correlated with the diameter of the aneurysm.[1] The mortality from aneurysm repair itself, however, can be significant.[2] Operative risk must be balanced against the risk of rupture when deciding between repair and observation. Repair is indicated in most patients with larger aneurysms, but two prospective randomized clinical trials failed to detect benefits of early open surgical repair compared with surveillance in patients with small aneurysms of <5.5 cm in diameter.[3,4]

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Operative mortality rates of 2.7% and 5.8% in these two trials raised the question of whether a procedure with lower operative mortality might provide benefit compared with observation in patients with smaller aneurysms, and endovascular aneurysm repair (EVAR) has been shown to have a lower perioperative mortality rate than open surgical repair.[5-7] The Positive Impact of Endovascular Options for Treating Aneurysms Early (PIVOTAL) trial was organized to determine whether early EVAR reduced the risk of rupture or aneurysm-related death compared with surveillance in patients with small (4- to 5-cm) abdominal aortic aneurysms (AAAs). Here we report the early results of this first randomized clinical trial comparing the two modalities.

METHODS

Study design. The trial was approved by the human subject research committees of each participating center. The trial management was coordinated centrally by a steering committee, and the safety of the study was monitored by an independent patient safety committee that met biannually.

Eligible patients were aged between 40 and 90 years, with infrarenal AAAs between 4.0 and 5.0 cm in diameter by computed tomography (CT) performed ≤3 months of screening. Patients were excluded from the study if they

had evidence of symptoms referable to the aneurysm, an abdominal or thoracic aortic repair, an aneurysm originating ≤1.0 cm from the most distal main renal artery, life expectancy of <3 years, inability to provide informed consent, predicted noncompliance with the protocol, Society for Vascular Surgery (SVS) score >2, with the exception of age and controlled hypertension, baseline serum creatinine level >2.5 mg/dL, or when the patient did not meet the indications for use for the endograft device. The Cleveland Clinic coordinating center managed the study and was responsible for randomization, study patient monitoring, data acquisition, and data analysis. The study is registered on clinicaltrials.gov (NCT00444821).

Randomization, treatment, and follow-up. The randomization procedure was created with equal probability of assignment to each of the treatment groups by means of a computer-generated random-number code that was maintained at the coordinating center. Patients assigned to early EVAR underwent aneurysm repair ≤30 days of randomization using any approved Medtronic endograft system (Medtronic, Santa Rosa, Calif). Before April 16, 2008, the implanted devices were the commercially available AneuRx device. After approval of the Talent device on April 2008, investigators could choose between the two. Follow-up analyses were scheduled for 1 month, 6 months, and every 6 months thereafter for a minimum of 36 months to a maximum of 60 months after operation. Imaging studies were scheduled for the 1-month, 6-month, and yearly visits and included CT scan with contrast, magnetic resonance scan, or a CT without contrast plus a duplex ultrasound study.

Individuals in the surveillance group were scheduled to undergo assessments every 6 months for a minimum of 36 months up to 60 months after randomization. An ultrasound or CT scan was performed at each assessment to assess the size of the aneurysm. Patients were offered aneurysm repair when symptoms thought referable to the aneurysm developed, when the diameter of the aneurysm reached 5.5 cm, or when the aneurysm enlarged ≥0.5 cm between any two 6-month assessments. When one of these criteria was met, endovascular or open surgical repair was advised.

Outcome measures. The primary objective of the trial was to determine whether early endovascular repair of aneurysms 4.0 to 5.0 cm in diameter is superior to surveillance with respect to the frequency of rupture or aneurysm-related death. The primary end point was the composite end point of rupture or aneurysm-related death, assessed through 3 years after randomization. Death was considered to be aneurysm-related when it occurred as a result of rupture or when it occurred ≤30 days of any operative procedure for aneurysm repair, whether the procedure was the primary endovascular or open repair, or a secondary procedure for remediation of problems from the first repair.

Statistical analysis. The sample size was based on the primary outcome of time to rupture or aneurysm-related death. The event rate for the composite outcome was estimated to be 1.7% per year in the surveillance group and 0.7% in the EVAR group corresponding to a hazard ratio of 0.42 (0.71/1.70) for surveillance vs early EVAR.[3,8,9] Sample size calculations assumed that the primary outcome would be evaluated 3 years after enrollment of the last patient, a 2.5-year accrual time, and an 18% loss to follow-up that would follow an exponential distribution. These estimates suggested that 1050 total patients, or 525 per group, would be necessary to detect a hazard ratio of ≤0.42 with 80% power at a significance level of 0.05. The estimates also assumed a constant hazard over time, but the actual analyses would account for nonconstant hazard in either or both groups.

Analyses of the primary end point and overall mortality were performed on an intent-to-treat basis using the log-rank test. Differences in the risk of end points between treatment groups were described using hazard ratios from Cox models. Kaplan-Meier analysis was used to estimate rates of other events during follow-up. Categoric factors were compared between treatment groups using χ^2 or Fisher's exact tests, and continuous measures were compared using *t* tests. Analyses were performed using StatView 9.1 software (SAS Institute, Cary, NC), and all comparisons assumed a .05 significance level.

RESULTS

Study group. Among 4665 patients screened, 728 (15.6%) were randomized (Fig 1). Of the 631 men (86.7%) and 97 women (13.3%), 366 were assigned to early endovascular repair and 362 to ultrasound surveillance. The mean initial diameter was 4.5 ± 0.3 cm in both groups. Mean ages were 70.5 ± 7.8 years for patients assigned to the early EVAR and 70.5 ± 7.7 years for those assigned to surveillance. Other baseline characteristics are listed in Table I. The only significant difference between the two treatment arms was a higher rate of neurologic disease in the early repair group ($P = .03$). The mean follow-up was 20 ± 12 months (range, 0-41 months) in each treatment group.

Aneurysm repair. Patients assigned to the early EVAR treatment arm underwent aneurysm repair a mean of 29.5 days (95% confidence interval [CI], 25-34 days) days after

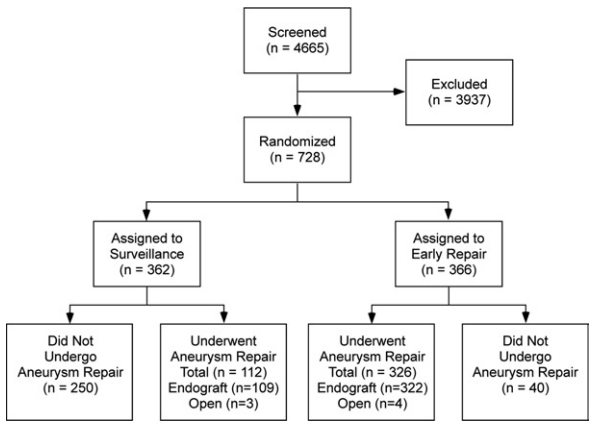

Fig 1. Flow chart shows patients, randomization, and outcomes.

Table I. Patient baseline characteristics

Variable	*Surveillance*	*Early repair*	P[a]
Demographics			
Age, mean (SD)	70.47 (7.67)	70.46 (7.80)	.99
Male gender, n/N (%)	306/362 (84.5)	325/366 (88.8)	.09
White race, n/N (%)	343/362 (94.8)	340/366 (92.9)	.3
Baseline AAA size, mean (SD) cm	4.45 (0.27)	4.45 (0.27)	.8
Hispanic ethnicity, n/N (%)	7/362 (1.9)	7/366 (1.9)	.98
Creatinine, mean (SD) mg/dL	1.10 (0.27)	1.14 (0.29)	.10[b]
Tobacco use, n/N	316/344 (91.9)	317/352 (90.1)	.41
Medication use, n/N (%)			
Antithrombotic therapy	278/347 (80.1)	281/349 (80.5)	.89
Antiplatelet agents	259/278 (93.2)	267/281 (95.0)	.35
Warfarin	32/278 (11.5)	29/281 (10.3)	.65
ACE inhibitor	150/347 (43.2)	136/351 (38.7)	.23
β-blocker	177/347 (51.0)	184/350 (52.6)	.68
Lipid-lowering	272/347 (78.4)	267/351 (76.1)	.47
Medical history, n/N (%)			
Family history of aneurysmal disease	77/295 (26.1)	62/298 (20.8)	.13
Cardiovascular history			
Myocardial infarction	106/337 (31.5)	107/344 (31.1)	.92
Congestive heart failure	22/339 (6.5)	21/353 (5.9)	.77
Coronary artery disease	195/345 (56.5)	190/350 (54.3)	.55
Cardiac arrhythmia	70/331 (21.1)	59/341 (17.3)	.21
Thrombolysis	22/330 (6.7)	12/333 (3.6)	.07
Peripheral vascular disease	92/333 (27.6)	99/344 (28.8)	.74
Hypertension	267/349 (76.5)	279/353 (79.0)	.42
Abdominal surgery	137/344 (39.8)	135/351 (38.5)	.71
Other disease history			
Pulmonary disease	80/340 (23.5)	73/344 (21.2)	.47
Renal disease	0/350 (0.0)	0/355 (0.0)	NA
Endocrine disease	76/351 (21.7)	70/354 (19.8)	.54
Infectious disease	3/333 (0.9)	2/341 (0.6)	.68[c]
Gastrointestinal	136/342 (39.8)	133/353 (37.7)	.57
Liver disease	8/342 (2.3)	10/352 (2.8)	.68
Cancer	85/348 (24.4)	91/352 (25.9)	.66
Neurologic disease	41/350 (11.7)	62/355 (17.5)	.03

AAA, Abdominal aortic aneurysm; *ACE,* angiotensin-converting enzyme inhibitor; *NA,* not applicable; *n/N,* number of events/number at risk; *SD,* standard deviation.

[a]Derived from Pearson χ^2 test unless otherwise specified.

[b]Derived from two-sample *t* tests assuming unequal variances.

[c]Fisher's exact test.

entry into the study. Among 322 patients in the early repair group who underwent an attempt at endovascular repair with a protocol device and within the specified time window, 321 (99.7%) had successful delivery and deployment. Among the 40 patients who did not receive the specified therapy, 6 underwent repair outside of the 30-day window after randomization, 9 were withdrawn at the patient's request, 10 were withdrawn by the treating physician for deteriorating health status between randomization and scheduled repair, and 2 were treated with an endograft device that was not in the protocol. The reasons for nonrepair in the remaining 13 patients were unspecified. Data outlining the outcome measures in the two groups are listed in Table II.

Endovascular procedures averaged 125 minutes in duration (95% CI, 118-132 minutes). The estimated blood loss of the procedures was 254 mL (95% CI, 225-283 mL). The length of hospital stay averaged 1.6 days (95% CI, 1.5-1.7 days). Graft limb thrombosis occurred in 18 patients through one year, with similar frequency in the early-EVAR group (13 patients, 4.8%) and the surveillance group (5 patients, 5.8%). An endoleak was documented in 36 patients (11.9%) at 30 days and in 72 (26%) at some time ≤1 year after the initial procedure. After repair, aneurysm enlargement by >0.5 cm was observed in 15 patients (5.7%) at 1 year of follow-up.

In the surveillance arm, 112 patients (30.9%) underwent aneurysm repair (Fig 2). The average time from randomization to repair was 370 days, and the average size of the aneurysms at the last imaging report before repair was 4.9 cm (range, 4.0-6.5 cm). Among these, 109 (97.3%) underwent EVAR and 3 (2.7%) had an open surgical repair. The most frequent reasons for aneurysm repair in the surveillance group were growth of the aneurysm in 77 (70.6%), patient anxiety and request for repair in 12 (11.0%), and the development of aneurysm-related symptoms in 8 (7.4%). The rate of aneurysm repair in the surveillance group increased with increasing baseline diam-

Table II. Frequency of the major end points in surveillance and early endovascular repair treatment groups

Measure	*Surveillance No. (%)*[a]	*Early EVAR No. (%)*[a]
Randomized patients	362/728 (49.7)	366/728 (50.3)
Received endograft device	109/362 (30.1)	322/366 (88.9)
Open surgery	3/362 (0.8)	5/366 (1.4)
Received repair	112/362 (30.9)	326/366 (89.1)
Successful delivery	109/109 (100)	321/322 (99.7)
Successful deployment	109/109 (100)	321/322 (99.7)
Rate of endograft implant		
4.00-4.25	19/102(18.6)	86/96 (89.6)
4.26-4.50	36/116 (31.0)	109/120 (90.8)
4.51-4.75	24/73 (32.9)	65/69 (94.2)
4.76-5.00	30/55 (54.6)	51/59 (86.4)
Rate of repair (open and endograft)		
4.00-4.25	20/102 (19.6)	87/96 (90.6)
4.26-4.50	37/116 (31.9)	110/120 (91.7)
4.51-4.75	24/73 (32.9)	65/69 (94.2)
4.76-5.00	31/55 (56.4)	53/59 (89.8)
30-day overall mortality		
From randomization	0/362 (0.0)	1/366 (0.3)
From repair	1/109 (0.9)	1/322 (0.3)
Overall mortality	15/362 (4.1)	15/366 (4.1)
Composite end point	2/362 (0.6)	2/366 (0.5)
Aneurysm rupture	1/362 (0.3)	0/366 (0.0)
Aneurysm-related mortality	1/362 (0.3)	2/366 (0.5)
Secondary interventions	5/109 (4.6)	12/322 (3.7)
Secondary interventions, No.		
1	4/109 (3.7)	11/322 (3.4)
2	1/109 (0.9)	1/322 (0.3)
Surgery ≤30-day randomization window	13/351 (3.7)	254/353 (72.0)

EVAR, Endovascular aneurysm repair.
[a]The data are number of patients (percent).

eter of the aneurysm at the time of randomization. The rate of repair was 19.6% among patients with aneurysm diameters of 4.00 to 4.25 cm compared with 56.4% in patients with aneurysms with diameters of 4.75 to 5.00 cm.

Mortality. The 30-day operative mortality rate in the early EVAR group was 0.6% (2 of 322). There were no deaths ≤30 days of randomization in the surveillance group. Among 109 surveilled patients who eventually underwent aneurysm repair, the 30-day operative mortality was 0.9% (1 of 109). After a mean follow-up of 20 ± 12 months (range, 0-41 months), there were 15 deaths in each group (4.1%), and the unadjusted hazard ratio for mortality in the early-EVAR group was 1.01 (95% CI, 0.49-2.07, $P = .98$; Fig 3).

Rupture or aneurysm-related death. Aneurysm rupture or aneurysm-related death occurred in two patients (0.6%) in the early EVAR group and in two patients (0.6%) in the surveillance group. One patient in the early-EVAR group died of multisystem organ failure during the hospitalization for aneurysm repair, and the second died of a fall-related intracranial hemorrhage ≤30 days after a secondary procedure to treat an endoleak. One patient in the surveillance group experienced aneurysm rupture and survived emergency EVAR. A second patient in this group underwent EVAR and died ≤30 days of the procedure.

The primary end point—time to rupture or aneurysm-related death—was similar in the two treatment groups (Fig 4). The unadjusted hazard ratio was 0.99 (95% CI, 0.14-7.06, $P = .99$) in the early EVAR group. There was no evidence of nonproportional hazards between the two groups over time; survival was similar in the two groups early as well as later after randomization.

Other perioperative complications and secondary procedures. Major perioperative complications in the patients who underwent aneurysm repair in the early EVAR group (322 patients) and the surveillance group (112 patients) are listed in Table III. The most frequent complications were vascular, usually at the femoral entry site, followed by wound infections, cardiac events, and pulmonary complications. Endograft migration occurred in two patients through 1 year of follow-up; one was in a patient in the early EVAR group (0.3%) and the other was in a patient initially randomized to surveillance (1.3%). Graft limb thrombosis occurred in 18 patients through 1 year at a similar frequency between groups, consisting of 13 patients (4.8%) in the early EVAR group and 5 (5.8%) in the surveillance group. Endoleaks were noted in just >10% of patients and were most often of the type II variety (Table IV).

There were 19 secondary procedures, including 8 procedures for graft limb occlusion, 9 for endoleak (2 for type I and 7 for type II leaks), and 2 for graft kinks or limb stenoses. There were 20 readmissions: 18 for secondary endovascular procedures and 2 for conversion to open repair after attempted endovascular graft implantation. Two patients in the early EVAR group required open surgical graft repair, one at 48 days after the endograft implantation due to iliac occlusion and one at 60 days after an unsuccessful attempted EVAR implant.

DISCUSSION

The prevalence of AAAs, a preventable cause of death, is increasing. Rupture of an aneurysm is unpredictable, rarely foreshowed by warning symptoms but lethal in up to 90%.[10] Recognition of these facts led to United States Congressional approval in 2007 of the SAAVE act to support ultrasound screening for aneurysms.[11] The risk of aneurysm rupture is related to aneurysm size, with large aneurysms more likely to rupture than small aneurysms. Treatment decisions for an individual patient are based on weighing the estimated risk of rupture against the estimated risk of death from treatment. Although the balance is clearly in favor of treating large aneurysms, there remains uncertainty for treating smaller aneurysms, and several prospective randomized trials have been conducted to address this question.

In this study, we sought to clarify the distinction between small and large aneurysms by defining small aneurysms as those <5.0 cm in diameter. Aneurysms of this size can rupture: the United Kingdom Small Aneurysm Trial (UKSAT) reported a rupture rate of approximately 1% per year.[1] When an AAA is detected, the

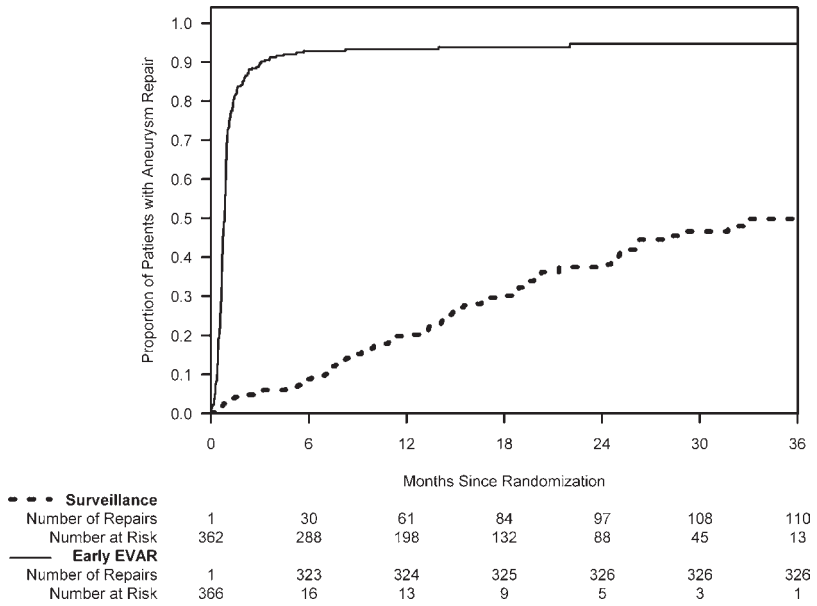

Fig 2. Cumulative rate of repair of abdominal aortic aneurysm according to assignment to surveillance *(dashed line)* or early endovascular aneurysm repair (*EVAR, solid line*).

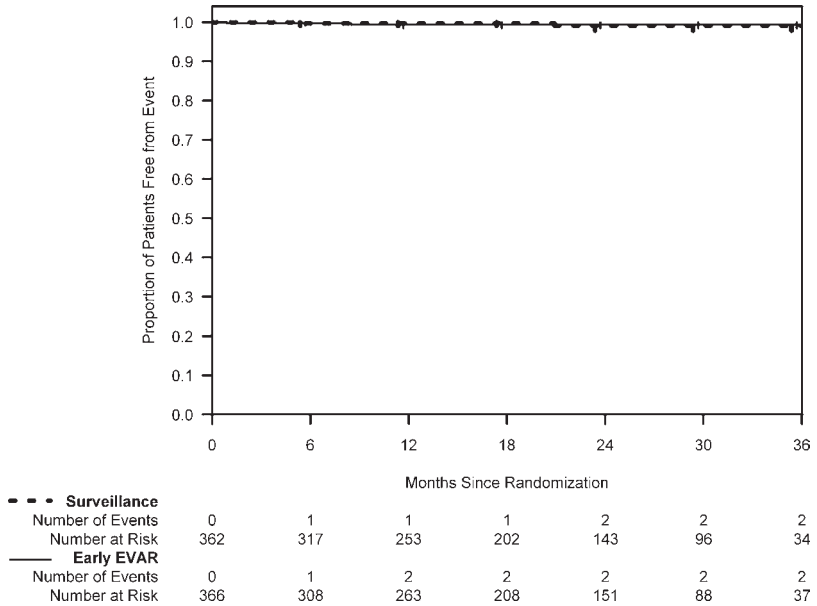

Fig 3. Kaplan-Meier estimates show the composite end point of aneurysm-related death or aneurysm rupture according to assignment to surveillance *(dashed line)* or early endovascular aneurysm repair *(EVAR, solid line)*. The time to the composite end point did not significantly differ between groups ($P = .99$).

patient and the clinician must determine whether repair or observation is indicated, a decision that is based on the relative risk of aneurysm rupture compared with the risk of repair.

Two randomized trials of patients with small aneurysms failed to detect benefit with early open surgical repair compared with surveillance:

- The UKSAT randomly assigned 1090 patients with 4.0- to 5.5-cm aneurysms to early open surgical repair or ultrasound surveillance. Survival after 8 years of follow-up was 7% greater in the early surgery group, a finding limited to that specific time point and one that was attributed to a higher rate of smoking cessation in the surgical group.[8]

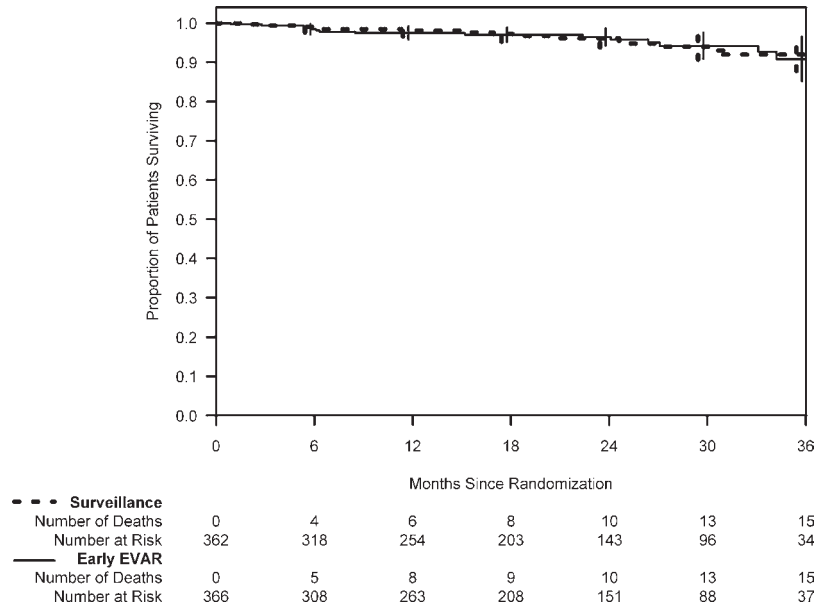

Fig 4. Kaplan-Meier estimates of overall survival with 95% confidence limits are shown according to assignment to surveillance (dashed line) or early endovascular aneurysm repair *(EVAR, solid line)*. Overall survival did not significantly differ between groups ($P = .98$).

Table III. Adverse events (<30 days) in the early endovascular repair group and the surveillance group among patients who underwent aneurysm repair (tabulated by number of occurrences)

	Group		
Adverse events	*Early EVAR (n = 322)*	*Surveillance (n = 112)*	*Total*
Endoleak	27	8	35
Endograft limb thrombosis	4	3	7
Endograft migration	1	0	1
Vascular complications	10	3	13
Deep venous thrombosis	1	0	1
Superficial wound infection	8	1	9
Other serious wound infections	3	1	4
Distal embolization to LE	1	1	2
Prolonged ileus (>4 d)	4	0	4
Prolonged fever (>4 d)	3	0	3
Q-wave myocardial infarction	1	1	2
Other serious cardiac events	6	5	11
Mesenteric ischemia	1	0	1
Multisystem organ failure	1	0	1
Prolonged intubation (>24 h)	1	0	1
Other serious pulmonary events	3	1	4
Transient creatinine increase	2	0	2
Persistent creatinine increase	0	1	1
Temporary hemodialysis	1	0	1
Other serious renal events	3	0	3

EVAR, Endovascular aneurysm repair; *LE,* lower extremities.

- The Aneurysm Detection and Management (ADAM) Veterans Affairs Cooperative Study assigned 569 patients with 4.0- to 5.4-cm aneurysms to open repair or surveillance, and the observations were similar to those of the United Kingdom group.

Table IV. Endograft migration, graft limb thrombosis, and endoleak

Measure	*Surveillance No. (est %)*	*Early EVAR No. (est %)*
Stent migration, 1 y	1 (1.3)	1 (0.3)
Thrombosis, 1y	5 (5.8)	13 (4.8)
All endoleaks		
30 d	10 (10.3)	36 (11.9)
1 y	30 (35.1)	72 (26.1)
Type I endoleaks		
30 d	1 (1.0)	0 (0.0)
1 y	2 (2.4)	2 (0.7)
Type II endoleaks		
30 d	9 (9.3)	34 (11.3)
1 y	29 (33.4)	67 (24.4)
Type III endoleaks		
30 d	0 (0.0)	1 (0.3)
1 y	0 (0.0)	1 (0.3)
Type IV endoleaks		
30 d	0 (0.0)	1 (0.3)
1 y	0 (0.0)	2 (0.7)
Aneurysm enlargement, 1 y	35 (14.2)	15 (5.7)

Est, Estimated; *EVAR,* endovascular aneurysm repair.

Overall survival as an end point, however, may mask the beneficial effects of aneurysm treatment in prevention of rupture or aneurysm-related death. Most of the patients in both the UKSAT and ADAM studies died of non-AAA or treatment-related causes, and patients in both groups died at about the same rates.

The two studies of open surgical repair vs surveillance have been criticized with respect to the high operative mortality rates.[12] The United Kingdom trial, for instance,

documented a 30-day mortality rate of 5% in the early surgical group.[4] Noting data that suggest a lower operative mortality rate with EVAR,[5] we tested the hypothesis that the survival cross-over and payback of EVAR might occur earlier and differences might be more robust than what was observed after open surgical repair.

The early results of the present study confirm the safety of EVAR in patients with small 4- to 5-cm aneurysms. The rate of perioperative mortality was only 0.6%, and the 3-year rate of rupture or aneurysm-related mortality was near zero. This observation suggests that early EVAR would be of benefit in preventing rupture, provided the rate of aneurysm rupture is sufficiently high in the surveillance group. Unexpectedly, however, the observed risk of rupture in the surveillance group was significantly lower than predicted. Unless the risk of rupture increases in a nonlinear fashion over time, the chance of demonstrating differences in the primary outcome measure of rupture or aneurysm-related death was <1% in a futility analysis. This interim analysis was performed to determine whether continued enrollment would be likely to demonstrate benefit of one group over the other. In fact, the rate of aneurysm rupture would have to increase about eightfold in the surveillance group for any statistically significant difference to be observed at the end of the study. This futility analysis triggered the trialists' decision to close the trial to patient enrollment before its planned enrollment of 1050 patients but to continue with the planned follow-up of existing patients.

The reasons for the lower-than-expected rate of rupture in this study are unclear. Compared with prior series, the present study enrolled patients with smaller aneurysms who were more frequently treated with statins and β-blockers, medications that may prevent aneurysm enlargement or rupture.[13,14] Further, the present study mandated rigorous surveillance that resulted in aneurysm repair for >30% of the surveillance group 3 years after randomization, potentially lowering the rupture rate in this group. These results are strikingly similar to those in the surveillance arm of the UKSAT, in which small aneurysms were repaired in a significant proportion of patients after a relatively short period of observation.[4]

CONCLUSIONS

Until longer follow-up data from this study are available, early treatment with EVAR and image-based surveillance, and aneurysm treatment as clinically indicated, both appear to be safe alternatives for patients with small aneurysms of 4.0 to 5.0 cm in diameter. One must caution, however, that this recommendation is based on early data that might change as longer-term data accrues. Further, the finding must be taken in the context of the very low operative mortality rate after EVAR performed by the experienced trial surgeons and the diligence of the follow-up in the surveilled patients. Patients who are noncompliant with imaging protocols comprise a particularly challenging subgroup for whom neither surveillance with selected repair, endovascular repair, nor even open surgery provide a safe option. Efforts in this subgroup should be directed at education and active tactics to encourage follow-up imaging studies. For now, decisions should be individualized and based on the size of the aneurysm, the medical condition of the patient, the likelihood of the patient following a rigorous surveillance protocol, and the surgeon's expertise in EVAR.

AUTHOR CONTRIBUTIONS

Conception and design: KO, DG, KK, CZ
Analysis and interpretation: KO, DG, KK, CZ
Data collection: The Cleveland Clinic CRO
Writing the article: KO, CZ
Critical revision of the article: DC, KK
Final approval of the article: KO, DC, KK, CZ
Statistical analysis: KO
Obtained funding: KO, DC
Overall responsibility: KO

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